In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 21-1445V

HEATHER MARSHALL,	*	
	*	Chief Special Master Corcoran
	*	
Petitioner,	*	Filed: April 12, 2024
	*	
v.	*	
	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
	*	
Respondent.	*	
	*	

Laura Levenberg, Muller Brazil, Dresher, PA, for Petitioner.

Mary Holmes, U.S. Department of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On June 7, 2021, Heather Marshall filed this action seeking compensation under the National Vaccine Injury Compensation Program (the "Program").[2] ECF No. 1. Petitioner alleges that an influenza ("flu") vaccine she received on October 7, 2019, caused her to incur brachial neuritis.[3] *Id.* The parties have submitted expert reports and offered briefs so that the matter can be resolved via ruling on the record. *See* Petitioner's Motion, dated August 23, 2023 (ECF No. 29) ("Mot."); Respondent's Opposition, dated September 15, 2023 (ECF No. 30) ("Opp."). For the reasons stated in more detail below, I deny compensation.

[1] Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Decision will be available to the public in its present form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to § 300aa of the Act (but will omit that statutory prefix).

[3] As noted herein, Petitioner's alleged injury is sometimes described (both in the record and the expert reports) as "Parsonage Turner Syndrome," or neuralgic amyotrophy, but there is no dispute that these terms are synonymous with brachial neuritis.

I. Factual Background

Pre-Vaccination History

Petitioner was born on November 24, 1972. Ex. 1 at 7. She had a pre-vaccination medical history significant for carpal tunnel syndrome ("CTS"), narcolepsy, plantar fasciitis, herniated lumbosacral disc, right hip pain, mood disorder, anxiety, depression, myofascial pain syndrome, and allergic rhinitis. Ex. 3 at 28; Ex. 2 at 14–15. Two years before the relevant vaccination, Petitioner received physical therapy ("PT") in 2017 for treatment of jaw pain, and had received a diagnosis of "cervical disc disorder with radiculopathy, high cervical region." Ex. 5 at 22. And she attended twenty-nine PT sessions for back, hip, and jaw pain between March 23, 2016, and September 18, 2017. *Id.* at 6–8.

Vaccination and Subsequent Six Months

On October 7, 2019, Petitioner received a flu vaccine in her right deltoid. Ex. 1 at 7. One month later, on November 8, 2019, Petitioner contacted her neurologist, Lee P. Dresser, M.D., via e-mail stating:

> I received a flu shot on 10/7 in my right arm. I have had [a] loss of feeling in my face, extreme pain in my neck, back, shoulder [,] and arm. Now my right hip. I have continuous numbness as well as shooting pain and full throbbing pain where the shot was administered.

Ex. 3 at 22.

On November 12, 2019, Petitioner visited Dr. Dresser and reported migratory numbness in her right arm, clumsiness in her right hand while typing, and severe pain at her injection site followed by pain in her right lateral neck. Ex. 3 at 5. Upon examination, Dr. Dresser noted that "DTR [deep tendon reflex] is reduced in [the] right biceps and BR [brachioradialis] compared to [the] left. She has decreased pinprick over much of [the] right arm. Other DTRs in [the] arm and leg were intact" *Id.* at 6. Dr. Dresser prescribed a Medrol dose pack and noted that Petitioner "could have a relatively mild right brachial plexitis perhaps related to the flu vaccination." *Id.*

Six days later, on November 18, 2019, Petitioner again emailed Dr. Dresser, stating that the Medrol dose pack had been unhelpful and complaining of "waves of pain, tingling, and the feeling of [her] arm freezing." Ex. 3 at 21. Dr. Dresser recommended that Petitioner undergo an EMG of her right arm. *Id.* On December 6, 2019, Petitioner went to physician's assistant Coty Kalbach reporting several issues, including arm numbness and tingling. Ex. 2 at 54. Petitioner demonstrated "no focal deficits," but was again encouraged to undergo an EMG. *Id.* at 52, 54.

In late January 2020 (now more than three months post-vaccination), Petitioner saw Dr. Larry Chou at Premier Orthopedics, complaining of increasing pain on the right side of her neck, radiating to the right shoulder, weakness and cold sensation in the right arm, numbness and tingling in the right arm, and the ring and little fingers. Ex. 2 at 144. Petitioner further noted that her symptoms had begun within a week of receiving the flu vaccine. *Id.* Upon examination, Petitioner exhibited 5/5 bilateral upper extremity strength, 1+ reflexes bilaterally, a negative Roos[4] test and positive Tinel's[5] tests at her right elbow and wrists, bilaterally. *Id.* Petitioner also underwent an EMG—the results of which revealed "mild right and borderline left sensory demyelinating median neuropathies (carpal tunnel syndrome) without denervation at either wrist." *Id.* Dr. Chou recommended Petitioner wear a wrist splint at night for two weeks, that she undergo a cervical spine MRI and a brachial plexus ultrasound, and that she attend PT. *Id.* at 28, 144.

Dr. Chou subsequently wrote a letter to Dr. Dresser summarizing Petitioner's EMG findings and noting that Petitioner's symptoms reportedly began "within a day" of her vaccination. Ex. 3 at 26. In addition to recommending a wrist splint, Dr. Chou also proposed a carpal tunnel injection, with a carpal tunnel release should Petitioner's symptoms not improve. *Id.* Dr. Chou's impression recorded that Petitioner had experienced "neuropathic symptoms involving the right upper limb of unclear etiology," and the "differential diagnosis include[d] cervical radiculitis versus a non-neurogenic, on-vascular dynamic thoracic outlet syndrome." *Id.* at 27.

On February 3, 2020, Petitioner underwent an MRI of the cervical spine, which showed mild degenerative disc disease, uncovertebral and facet arthropathy, mild spinal canal stenosis at C4-C5, and mild right neural foraminal stenosis at C5-C6. Ex. 9 at 6.

Treatment for the Remainder of 2020 and Thereafter

Several months passed before Petitioner obtained additional treatment in connection with the alleged vaccine injury—a PT evaluation at Moore Therapeutic Services on June 1, 2020. Ex. 5 at 35. Upon examination, Petitioner demonstrated decreased flexion (160 degrees) and abduction (160 degrees) of the right shoulder and decreased external and internal range of motion. *Id.* at 36–37. She had full range of motion in both upper extremities, including elbows and wrists; normal reflex testing on both extremities; and no sensory or vascular deficits. *Id.* The physical therapist

[4] In a Roos test, "the patient raises the arms to 180° above the shoulders, abducts them, bends the elbows, and opens and closes the fists for 3 minutes; reproduction of symptoms is a positive outcome." *Roos test*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=112908&searchterm=Roos%20test (last visited Apr. 12, 2024).

[5] Tinel sign is defined as "a tingling sensation in the distal end of a limb when percussion is made over the site of a divided nerve. It indicates a partial lesion or the beginning regeneration of the nerve." *Tinel sign*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=106510 (last visited Apr. 12, 2024).

recommended weekly PT sessions, although Petitioner only underwent two sessions through August. *Id.* at 37, 40–41.

On September 23, 2020, Petitioner saw her primary care provider ("PCP"), Kathleen H. Willey, M.D. Petitioner now reported that her arm was improving from the flu shot injury she had allegedly incurred in October 2019. Ex. 13 at 7.

The next month, Petitioner visited osteopath Erich L. Gottwald, D.O., who performed a second EMG study of her right upper extremity and provided his reaction/interpretation. Ex. 7 at 17–19. During her visit, Petitioner complained of pain in her right shoulder radiating into her hand and fingers, and "numbness/tingling in the elbow [that went] to her hand and fingers (her small and ring fingers are most bothersome)." *Id.* Upon examination, Petitioner exhibited a positive right-side carpal compression test, but normal strength, normal sensation, and intact reflexes in both upper extremities. *Id.* Dr. Gottwald documented Petitioner's EMG results as "abnormal"—noting that they revealed evidence of a "VERY MILD RIGHT carpal tunnel syndrome (median nerve entrapment at wrist) affecting sensory components. Since previous EMG on 1/2020 there has been no change." *Id.* (capitalization in original).

On June 2, 2021, Petitioner had a follow-up visit with Dr. Dresser, at which time she indicated that she still experienced upper left arm pain, which she attributed to her vaccination. *Id.*

II. Expert Reports/Treater Statements

A. *Petitioner's Expert – John D. Hixson, M.D.*

Dr. Hixson, a neurologist, offered two written reports for Petitioner. Report, dated Aug. 23, 2022, filed as Ex. 16-1 (ECF No. 21-2) ("Hixson First Rep."); Report, dated May 18, 2023, filed as Ex. 33-1 (ECF No. 25-2) ("Hixson Supp. Rep."). Dr. Hixson proposes that Petitioner experienced an acute right brachial plexus neuritis due to receipt of the flu vaccine.

Dr. Hixson attended Texas A&M University for his undergraduate degree, and Johns Hopkins University School of Medicine for his medical degree. *See* Curriculum Vitae, filed Aug. 29, 2022 (ECF No. 21-3) ("Hixson CV") at 1; Hixson First Rep. at 1. He then completed his residency in Neurology at the University of Pennsylvania, followed by a fellowship in Epilepsy and Neurophysiology at the University of Iowa. Hixson CV at 1. He is currently a Professor of Neurology at the San Francisco VA Medical Center and the University of California San Francisco. *Id.* at 2; Hixson First Rep. at 1. Dr. Hixson is board certified by the American Academy of Psychiatry and Neurology. Hixson First Rep. at 1. Clinically, he sees patients in both an outpatient and inpatient setting—on average, Dr. Hixson sees approximately 30-35 patients per week and evaluates and treats patients with brachial neuritis. *Id.* at 1–2.

First Report

Dr. Hixson first provided a brief overview of the pertinent medical records and facts before discussing Petitioner's diagnosis and his ultimate opinion in the matter. Hixson First Rep. at 2–4. He deemed Petitioner's clinical course "consistent with a diagnosis of Parsonage Turner Syndrome ["PTS"], which is characterized by acute onset of severe shoulder and upper arm pain, followed by neurologic symptoms of weakness, reflex changes, dysesthesias, and numbness in the affected region." *Id.* Petitioner's carpal tunnel issues, by contrast, predated her receipt of the flu vaccine and had no relationship to it, although this diagnosis was confirmed by her January 29, 2020 EMG study. *Id.* Petitioner's acute onset of symptoms and the temporal relationship to the vaccination showed that the vaccine was causally associated with development of her neurologic symptoms. *Id.*

As Dr. Hixson explained, PTS "is a neurological condition affecting the peripheral nerves in the brachial plexus, a large conduit for nerves located deep in the shoulder." Hixson First Rep. at 4; J.H. Feinberg & J. Radecki, *Parsonage-Turner Syndrome*, 6 HHS J. 199 (2010), filed as Ex. 18 (ECF No. 21-4) ("Feinberg"). It typically manifests with sudden, unilateral shoulder pain that amplifies quickly in severity—consistent with Petitioner's clinical course. *Id.*; J. Ijspeert et al., *Neuralgic Amyotrophy*, 34 Curr Opin Neurol 1 (2021), filed as Ex. 24 (ECF No.21-10) ("Ijspeert"). While there are many possible causes of acute brachial neuritis/PTS, a "post-vaccination response" is well supported by the medical literature and is the second most common risk factor for developing it. Hixson First Rep. at 4; Feinberg at 2. It nevertheless remains unclear how PTS initiates, but "a prevailing theory is that as a part of the immune-mediated inflammatory response associated with vaccination, auto-antibodies are created which in rare cases can attack the body's own nervous system." Hixson First Rep. at 4; *Parsonage Turner Syndrome*, Genetic and Rare Diseases Information Center, https://beta.rarediseases.info.nih.gov/diseases/4228/parsonage-turner-syndrome (last updated June 15, 2017); G.A. Suarez et al., *Immune Brachial Plexus Neuropathy: Suggestive Evidence for an Inflammatory-Immune Pathogenesis*, 46 Journal Info 559 (1996), filed as Ex. 27 (ECF No. 21-13).

Dr. Hixson next discussed the evidence that he opined supported vaccination as the reason for Petitioner's injury. Hixson First Rep. at 5. Petitioner had received her flu vaccine on October 7, 2019, and over the course of the next month began experiencing progressive symptoms which resulted in her seeking medical treatment. *Id.* This course, Dr. Hixson proposed, is the "standard clinical description for an autoimmune-mediated process following vaccination." *Id.* Moreover, Petitioner's neurological findings on November 12, 2019, were consistent with a diagnosis of acute brachial neuritis—including evidence of a diminished set of reflexes and sensory findings. *Id.*; Ex. 3 at 4. Thus, the nature and onset of Petitioner's symptoms were "entirely consistent with a post-vaccination response." Hixson First Rep., at 5.

In contrast, her history of CTS was neither related to nor causative of her brachial neuritis. Hixson First Rep. at 5. The pathogenesis of CTS—local irritation and nerve impingement to the wrist—is both too distant to the pathology of brachial plexus, Dr. Hixson maintained, and is a chronic condition that typically does not play a causative role in an acute inflammatory response. *Id.*

Finally, Dr. Hixson addressed the temporal relationship between vaccination and Petitioner's injury. Hixson First Rep. at 5. He noted that PTS typically "begins with acute pain in the shoulder region (evolving over days), followed by progressive (but limited) weakness and numbness in the affected limb." *Id.* Here, Petitioner had reported to her doctor that her symptoms—pain, weakness, and numbness—began on November 8, 2019, approximately one-month post-vaccination. *Id.*; Ex. 3 at 20. This reflected the "natural evolution" of PTS. *Id.* at 5–6.

Supplemental Report

Dr. Hixson's next report responded to the opinions and conclusions of Respondent's experts (Drs. Anand and Miner). Hixson Supp. Rep. at 1. He first expressed disagreement with Dr. Anand's contention that Petitioner did not suffer from brachial neuritis, but instead CTS due to the lack of typical examination findings. *Id.* Dr. Hixson reasoned that a "diagnosis of brachial neuritis is not always perfectly dichotomous," and that physicians typically need to consider the symptoms, the timing, and the objective test results collectively to make the diagnosis. *Id.*; Feinberg at 199. The medical literature strongly supports the notion of clinical variability regarding the presentation and timing of brachial neuritis. Feinberg at 199. Here, Petitioner's medical records demonstrate objective neurologic findings, including reduced and asymmetric reflexes in the right arm with reduced sensation. Moreover, Dr. Hixson argued, "[e]ven if the neurologic examination did not demonstrate frank weakness, these are still objective and documented neurologic findings that are consistent with brachial neuritis." *Id.* at 2.

Dr. Hixson further maintained that other medical record evidence did not undermine a brachial neuritis diagnosis. Hixson Supp. Rep. at 2. Although Dr. Anand had emphasized the EMG findings as mainly consistent with CTS, that diagnosis would not explain the symptoms Petitioner experienced in her shoulder and upper arm, nor would CTS cause depressed reflexes in the biceps or brachioradialis, or loss of sensation throughout her upper arm. *Id.* At bottom, in Dr. Hixson's opinion, Petitioner's CTS was independent of the neurologic symptoms Petitioner developed post-vaccination. *Id.*

Dr. Hixson also briefly responded to Dr. Miner's comments regarding the proposed alternative diagnosis of cervical radiculopathy. Hixson Supp. Rep. at 2. Dr. Miner had referred to Petitioner's MRI findings and EMG studies as suggestive of cervical radiculopathy, noting that "nerve conduction studies are often normal in neuralgic amyotrophy [which] neuralgic

amyotrophy can be difficult to distinguish from cervical radiculopathy." *Id.* Dr. Hixson agreed with this assertion, and even noted that cervical radiculopathy was reasonably included in Petitioner's differential diagnosis. But he maintained that Dr. Miner had failed to give enough weight to the timing and evolution of Petitioner's symptoms, reasoning that "[i]f a cervical radiculopathy was causative, it would require an unusual coincidence to present so suddenly and temporally associated to the vaccine administration." *Id*. He further stated that "MRI findings of degenerative disc disease with mild canal narrowing and moderate neuroforaminal stenosis are also common incidental observations, and many patients will have no referrable symptoms from these." *Id.* Hence, Dr. Hixson opined that the acute evolution of pain and the temporal association with Petitioner's receipt of the flu vaccine "continue to make brachial neuritis the more likely diagnosis." *Id.*

B. *Respondent's Expert — Pria Anand, M.D.*

Dr. Anand, a neurologist, authored two reports for Respondent. Report, dated Oct. 4, 2022, filed as Ex. A (ECF No. 22-1) ("Anand First Rep."); Report, dated June 15, 2023, filed as Ex. G (ECF No. 26-1) ("Anand Supp. Rep."). Dr. Anand opined that Petitioner's medical records do not support a diagnosis of brachial neuritis; instead, she had CTS which preceded her receipt of the flu vaccine.

Dr. Anand attended Yale University for her undergraduate degree, and Stanford University for her medical degree. Curriculum Vitae, filed as Ex. B (ECF No. 22-2) ("Anand CV") at 1. She then completed an internship in Internal Medicine at the University of North Carolina Hospital and Clinics, followed by her residency in Neurology at Johns Hopkins Hospital. *Id.* Thereafter, Dr. Anand completed a fellowship in Infectious, Inflammatory, and Advanced General Neurology at Massachusetts General Hospital. *Id.*; Anand First Rep. at 1. She is currently an Attending Physician and Assistant Professor of Neurology at the Boston University School of Medicine and the Boston Medical Center. Dr. Anand also frequently evaluates patients with brachial neuritis/Parsonage Turner Syndrome and other neurologic complications due to vaccination in both an outpatient and inpatient setting. Anand First Rep. at 1–2. Dr. Anand is board certified by the American Board of Psychiatry and Neurology, and she has also published extensively on topics in neurology. Anand CV at 1, 9–13; Anand First Rep. at 2.

First Report

Dr. Anand provided a brief overview of the medical facts and circumstances of this case before offering her opinion. Anand First Rep. at 2–4. She also described PTS/brachial neuritis. *Id.* at 4–5. Although certain kinds of testing (in particular, MRI and ultrasound of the brachial plexus) can support the existence of brachial neuritis, "it is primarily a clinical diagnosis, made by history and physical exam and supported by electrodiagnostic testing." *Id*. at 4. Common physical examination findings include "weakness with confrontational strength testing, atrophy (or loss of

muscle bulk as a consequence of denervation), and 'scapular winging,' or protrusion of the scapula as a consequence of injury to the long thoracic nerve." *Id.*; N. van Alfen & B. van Engelen, *The Clinical Spectrum of Neuralgic Amyotrophy in 246 Cases*, 129 Brain 438 (2006), filed as Ex. C3 (ECF No. 22-5); J. Van Eijk et al., *Neuralgic Amyotrophy: An Update on Diagnosis, Pathophysiology, and Treatment: Neuralgic Amyotrophy Update*, 53 Muscle Nerve 337 (2016), filed as Ex. C4 (ECF No. 22-6).

Dr. Anand questioned whether there was sufficient evidence in the medical records to support a brachial neuritis diagnosis. Anand First Rep. at 4. In her view, electrodiagnostic testing often reveals denervation as soon as two to three weeks after the onset of symptoms in patients with brachial neuritis/PTS. *Id.*; M. Ferrante, *Brachial Plexopathies*, 20 Contin Minneap Minn 1323 (2014), filed as Ex. C1 (ECF No. 22-3); M. Ferrante & A. Wilbourn, *Lesion Distribution among 281 Patients with Sporadic Neuralgic Amyotrophy*, 55 Muscle Nerve 858 (2017), filed as Ex. C2 (ECF No. 22-4). But in this case, Petitioner's electrodiagnostic testing (performed on January 29, 2020—meaning *more* than three months post-vaccination) showed only "mild right and borderline left sensory median neuropathy at the wrist *with no evidence of denervation*." Anand First Rep. at 4 (emphasis added); Ex 4 at 5. Petitioner also underwent repeat testing approximately one year after the onset of her symptoms, but it only confirmed the presence of "very mild right Carpal Tunnel Syndrome (median nerve entrapment at wrist affecting sensory components)." Anand First Rep. at 4; Ex. 7 at 17. Thus, a critical diagnostic indicator for PTS was absent from Petitioner's medical record.

Other clinical evidence from the medical record was also deemed by Dr. Anand to be unsupportive of the proposed brachial neuritis diagnosis. Petitioner underwent multiple physical examinations following the onset of her symptoms, "none of which document muscle weakness, atrophy, or scapular winging—the absence of such motor deficits is inconsistent with a diagnosis of brachial neuritis/PTS." Anand First Rep. at 4. Indeed, several "physical examinations document that [Petitioner exhibited] full strength throughout her right arm and shoulder." *Id.*; Ex. 3 at 6 (Nov. 12, 2019, appointment with Dr. Dresser documenting good strength in both of Petitioner's arms); Ex. 4 at 9 (Jan. 29, 2020, appointment with Dr. Chou stating "[b]ilateral shoulder forward flexion, abduction, internal and external rotation range of motion is grossly functional and symmetric. Strength testing is 5/5 in the deltoid, biceps, triceps, wrist extensors, finger flexors, and hand intrincsics as well as grossly in the neck and spine.").

Dr. Anand next discussed the timing and duration of Petitioner's symptoms. Anand First Rep. at 6. Even if Petitioner exhibited *some* symptoms of "mild BN/PTS" close in time to her receipt of the flu vaccine, those symptoms were not corroborated by the physical examinations or electrodiagnostic findings, and had likely resolved by the time of Petitioner's January 2020 examination (hence less than three months post-vaccination). *Id.* And while Dr. Anand acknowledged that Petitioner underwent a right ring trigger finger release in November 2020, she

noted that this injury was sustained "after weeding in [Petitioner's] garden—thus, unrelated to both the vaccination and the patient's reported diagnosis of BN/PTS and CTS." *Id.*

Supplemental Report

In her supplemental report, Dr. Anand responded to some of Dr. Hixson's comments. Anand Supp. Rep. at 1. Dr. Anand criticized Dr. Hixson's contention that "the absence of weakness and findings on electromyography (EMG) to suggest brachial neuritis do not conclusively exclude a diagnosis of brachial neuritis." *Id.* (citing Hixson Supp. Rep. at 1–2). She argued that Dr. Hixson's contention ignored the possibility of an alternative condition, cervical radiculopathy—supported by objective findings—which could explain Petitioner's symptoms. Anand Supp. Rep. at 1.

Dr. Anand also disagreed with Dr. Hixson's assertion that the close timing of Petitioner's symptoms argued against cervical radiculopathy as the cause of her symptoms. Anand Supp. Rep. at 1 (citing Hixson Supp. Rep. at 2). In fact, the record showed that Petitioner's symptoms had not suddenly manifested "within weeks of the vaccine administration," but instead that Petitioner had begun reporting right-sided neck pain as early as 2017 (although other symptoms began at the time of injection and continued over the next several days). Anand Supp. Rep. at 2; Ex. 5 at 12; Ex. 3 at 29. In fact, Dr. Anand maintained, acute onset at the time of vaccination was inconsistent with an immune-mediated mechanism of injury. Anand Supp. Rep. at 2. This, plus (a) the lack of EMG support for brachial neuritis, coupled with (b) the MRI support for cervical radiculopathy, suggested to Dr. Anand that a vaccine-caused brachial neuritis was not corroborated by the record. *Id.*

C. *Respondent's Second Expert - Jonathan Miner, M.D., Ph.D.*

Dr. Miner, a rheumatologist, authored one report for Respondent. Report, dated Dec. 16, 2022, filed as Ex. F (ECF No. 23-2) ("Miner Rep."). Dr. Miner opined that Petitioner's receipt of the flu vaccine did not cause or exacerbate her pain and associated neurological symptoms.

Dr. Miner attended Brigham Young University ("BYU") for his undergraduate degree, and the University of Oklahoma, College of Medicine for his Ph.D. in Biochemistry and medical degree. Curriculum Vitae, filed as Ex. E (ECF No. 23-1) ("Miner CV") at 1. He then completed his residency in Internal Medicine followed by a fellowship in Rheumatology at Washington University and Barnes-Jewish Hospital in St. Louis, Missouri. Miner CV at 1. In addition, Dr. Miner completed a post-doctoral fellowship at the Michael S. Diamon Laboratory at Washington University. *Id.* He is currently an Associate Professor of Medicine and Microbiology at University of Pennsylvania Perelman School of Medicine, as well as the principal investigator of a research laboratory at the University of Pennsylvania. *Id.*; Miner Rep. at 1. Dr. Miner has evaluated and

treated hundreds of patients with rheumatologic diseases and continues to be active in clinical care. Miner Rep. at 1. He is board certified in Internal Medicine and Rheumatology, and he has published extensively on topics in rheumatology, microbiology, and immunology. Miner CV at 7–10; Miner Rep. at 1.

Dr. Miner summarized the pertinent medical facts and then briefly addressed his opinion as it relates to diagnosis and causation. Miner Rep. at 3–4. PTS is oftentimes "thought to be a process involving the axons of the neurons," and thus "during the early phases of the disease, one would expect to see 'widespread denervation in the involved muscles, and complete denervation is often the case.'" *Id.* at 3; Feinberg at 202. Dr. Miner then noted that a diagnosis of PTS is "very dependent on the EMG (needle) portion of the electrodiagnostic exam." *Id.* In fact, "[d]enervation and multifocal involvement in PTS" are supported by several articles Dr. Hixson had offered. Miner Rep. at 3; F. Vriesendorp et al., *Anti-Peripheral Nerve Myelin Antibodies and Terminal Activation Products of Complement in Serum of Patients with Acute Brachial Plexus Neuropathy*, 50 Ach Neurol. 1302 (1993) (finding that patients demonstrated involvement of *some* nerves and not others, which was confirmed by EMG and NCS); G. Suarez et al., *Immune Brachial Plexus Neuropathy: Suggestive evidence for an Inflammatory-Immune Pathogenesis*, 46 Neurology 559 (1996) (suggesting that EMG studies revealed denervation or demyelination in all four studied patients).

Petitioner's medical records, Dr. Miner opined, revealed that she suffered from shoulder and neck pain, numbness, and was later diagnosed with CTS as an explanation for her symptoms involving her hand. Miner Rep. at 3. While a contemporaneous exam by Dr. Dresser in November 2019, resulted in some findings consistent with brachial neuritis (due to evidence of diminished reflexes and sensation), in Dr. Miner's view cervical radiculopathy and brachial neuritis/PTS "can easily be confused clinically." *Id.*; Feinberg at 202. Thus, the limited clinical proof in support of Petitioner's proposed diagnosis was not especially robust on its own.

Moreover, the medical records also revealed that Petitioner had degenerative arthritis, including neural foraminal stenosis on MRI, underscoring the extent to which Petitioner's "symptoms described cannot definitively be attributed [to] just one specific disease process, since there was undoubtedly more the one disease process [taking place]." Miner Rep. at 3. It was not uncommon, he added, for patients with shoulder and neck pain with associated weakness to later be diagnosed with moderate neural foraminal narrowing in the cervical spine. *Id.* Indeed, as relied upon by Dr. Hixson in Ijspeert, "nerve conduction studies are often normal in neuralgic amyotrophy, and 'neuralgic amyotrophy can be difficult to distinguish from cervical radiculopathy.'" *Id.*; Ijspeert at 5. Therefore, "based on the MRI evidence of degenerative arthritis on the right side of the cervical spine, [and] an EMG result without evidence of denervation," Dr. Miner opined that a diagnosis of degenerative arthritis with acute radiculopathy as the more likely explanation for Petitioner's constellation of symptoms. Miner Rep. at 4.

Regarding vaccine causation, Dr. Miner emphasized that Petitioner was later diagnosed with degenerative arthritis of the cervical spine in April 2017—which is understood to be a "wear-and-tear" type of arthritis that is not immunological in etiology. Miner Rep. at 4. Degenerative arthritis involves a gradual process, usually developing over time, although radicular symptoms can flare acutely. *Id.* at 5. But Dr. Miner could not identify any literature supporting the concept that degenerative arthritis or degenerative arthritis-related neuropathic symptoms could be vaccine-caused. *Id.* at 5. Thus, "there should be no suspicion that a vaccine could have caused the type of cervical spine arthritis that the Petitioner has," he concluded. *Id.* At most, there existed some data suggesting that the flu vaccine can induce other kinds of peripheral neuropathies—but Dr. Miner disputed that the record in this case supported the conclusion that Petitioner suffered from a vaccine-induced demyelinating or denervating process. *Id.* Rather, many of the symptoms she experienced could be better explained as attributable to degenerative arthritis of the cervical spine. *Id.* at 4–5. Not only was there a lack of evidence suggesting systemic inflammatory processes or denervation, but no evidence of an autoantibody-mediated process. *Id.* at 5.

III. Procedural History

As noted above, this case was initiated in the early summer of 2021, approximately three years ago, and assigned to a different special master. After the filing of medical records was completed, the matter was reassigned to me in February 2022. Thereafter, Respondent filed his Rule 4(c) Report contesting entitlement in March 2022. (ECF No. 19). The parties began the process of obtaining expert reports, with the final report from Dr. Anand filed in June 2023. I proposed a briefing schedule for a ruling on the record, and the matter is ripe for resolution.

IV. Parties' Arguments

Petitioner

Petitioner maintains that she has presented a persuasive medical theory causally connecting her brachial neuritis to the flu vaccine. Mot. at 6. She relies on Dr. Hixson's report, arguing that a "post-vaccination response is supported by the literature and research as being one likely cause of brachial neuritis." *Id.*; Hixson First Rep. at 4; M. Shaikh et al., *Acute Brachial Neuritis following Influenza Vaccination*, BMJ Case Reports 2012. doi:10.1136/bcr-2012-007673 (discussing a 46-year-old women complaining of acute onset of severe left shoulder pain developing days after receipt of the influenza vaccine); D. Marks, *Parsonage-Turner Syndrome Associated with Influenza Vaccination: A Case Report with Discussion of Vaccination Neurologic Complications and Causation*, 21 Internet J. of Neurology 1 (2019), filed as Ex. 31-1 (ECF No. 21-17) (describing a 61-year-old individual who presented with left shoulder pain and weakness and diagnosed with PTS following receipt of the influenza vaccine several weeks prior).

Petitioner further argues that a diagnosis of acute right brachial plexus neuritis following the flu vaccine was confirmed by her treating physicians, as well as objective findings in her physical examination. Mot. at 9; Hixson First Rep. at 4; Hixson Supp Rep. at 1; Ex. 3 at 4 (documenting reduced and asymmetric reflexes in Petitioner's right arm, including reduced sensation). And she contends that she has established a logical sequence of cause and effect showing that the vaccination was the reason for her injury. Mot. at 10. She notes that she received the flu vaccine on October 7, 2019, and that she then began experiencing progressive symptoms over the course of the next month. *Id.*; Ex. 1; Hixson First Rep. at 5. As stated in his reports, Dr. Hixson's understanding of the evolution of Petitioner's symptoms over the course of several weeks is consistent with an immune mediated process. Mot. at 11; Hixson First Rep. at 5. Moreover, Petitioner's treating neurologist, Dr. Dresser, attributed her brachial neuritis to her vaccination. Mot. at 11; Ex. 3 at 2–4.

Finally, Petitioner argues that she has established a proximate temporal relationship between vaccination and subsequent injury. Mot. at 12. In so asserting, Petitioner emphasizes her demonstrated symptoms over the course of the next several weeks post-vaccination, which she maintains demonstrate a "classic temporal relationship." *Id.*; Hixson First Rep. at 6. Based on the medical literature, the diagnosis from her treating neurologist, Dr. Dresser, and the opinions of Dr. Hixson, a qualified expert, Petitioner contends that she has put forth preponderant evidence establishing the onset of her symptoms occurred within a medically acceptable timeframe. Mot. at 12.

Respondent

Respondent argues that Petitioner has failed to meet the criteria required to establish entitlement to compensation under the Vaccine Act set forth in *Althen v. Sec'y of Health & Hum. Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). Opp. at 11. At the outset, he maintains that Petitioner has not established that she experienced brachial neuritis—noting that both Drs. Anand and Miner agree there is insufficient evidence to support the diagnosis. *Id.* Instead, "Petitioner's support for brachial neuritis as her diagnosis appears to consist only of self-reported, subjective shoulder weakness in November 2019, which lead [sic] Dr. Dresser to consider that [P]etitioner '*could* have relatively mild right brachial plexitis.'" *Id.* at 13; Ex. 3 at 6 (emphasis added). Moreover, Dr. Dresser's speculation about the propriety of a brachial neuritis diagnosis was never corroborated by any findings from Petitioner's multiple EMGs. Opp. at 14.

Next, Respondent argues that Petitioner has not produced reliable preponderant evidence that the flu vaccine can cause brachial neuritis—arguing that Dr. Hixson fails to adequately explain how the vaccine might initiate an immune-mediated inflammatory response, or how this response would lead to brachial neuritis. Opp. at 14. Instead, Dr. Hixson merely makes broad reference to medical articles, without any further explanation. *Id.* In addition, Respondent notes that "[i]t is

unclear whether Dr. Hixson endorses [molecular mimicry] as his theory since neither the Motion nor [his] reports directly reference molecular mimicry or any other specific causal mechanism." *Id.* at 15. Respondent contends that Dr. Hixson's conclusions are ultimately unsupported by the medical literature, as he has not provided any evidence that the flu vaccine can cause brachial neuritis via molecular mimicry or any other mechanism, and thus his opinions should be rejected. *Id.* at 17.

Respondent then maintains that Petitioner has not demonstrated a logical sequence of cause and effect that Petitioner's flu vaccine caused her brachial neuritis. Opp. at 17. As noted by Dr. Miner, "[P]etitioner suffered from three coinciding disease processes when she sought treatment: carpal tunnel syndrome, degenerative arthritis, and probable cervical radiculopathy." *Id.*; Miner Rep. at 3–4; Ex. 9 at 6. All the experts agree that Petitioner's CTS predated and is unrelated to her receipt of the flu vaccine, and thus that condition can explain the symptoms Petitioner experienced in her right-hand. Opp. at 17–18. In addition, as Dr. Miner opined, Petitioner's neurological symptoms involving the neck and shoulder area were more likely attributable to degenerative arthritis and cervical radiculopathy. *Id.* at 18; Miner Rep. at 3.

Lastly, Respondent contends that Petitioner failed to submit preponderant evidence of a medically-acceptable timeframe between vaccination and the onset of her reported brachial neuritis. Opp. at 19. Although Petitioner asserts that "her pain and subsequent weakness and numbness began on November 8, 2019, approximately [one] month after her vaccination," Petitioner has not provided any actual evidence that would illustrate how such a timeframe post-vaccination was medically-acceptable. *Id.*; Mot. at 12.

V. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[6] Although this matter was initially designated for the SPU (since claims that the flu vaccine can

[6] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. Appx. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

cause GBS are common in the Program, and hence frequently can be resolved in short order), There is no Table claim for brachial neuritis after receipt of the flu vaccine.

Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen*, 418 F.3d at 1278: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each of the *Althen* prongs requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden

placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245.

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *see also LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof" (citing *Moberly*, 592 F.3d at 1322)); *Howard v. Sec'y of Health & Hum. Servs.*, 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *appeal docketed*, No. 23-1816 (Fed. Cir. Apr. 28, 2023). Otherwise, petitioners *always* have the ultimate burden of establishing their Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs.*, 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious

for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review denied*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. denied after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. denied* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs.*, 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked

propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs.*, No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs.*, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs.*, 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later

testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs.*, 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs*., 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g*., *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs.*, 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs.*, No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed numerous items of medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted in this case, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

E. *Standards for Ruling on the Record*

I am resolving Petitioner's claim on the filed record, and the parties have not challenged my determination to do so. Mot. at 2; Opp. at 1. The Vaccine Act and Rules not only contemplate but encourage special masters to decide petitions on the papers where (in the exercise of their discretion) they conclude that doing so will properly and fairly resolve the case. Section 12(d)(2)(D); Vaccine Rule 8(d). The decision to rule on the record in lieu of hearing has been affirmed on appeal. *Kreizenbeck v. Sec'y of Health & Hum. Servs.*, 945 F.3d 1362, 1366 (Fed. Cir. 2020); *see also Hooker v. Sec'y of Health & Hum. Servs.*, No. 02-472V, 2016 WL 3456435, at *21

n.19 (Fed. Cl. Spec. Mstr. May 19, 2016) (citing numerous cases where special masters decided case on the papers in lieu of hearing and that decision was upheld). I am simply not required to hold a hearing in every matter, no matter the preferences of the parties. *Hovey v. Sec'y of Health & Hum. Servs.*, 38 Fed. Cl. 397, 402–03 (1997) (determining that special master acted within his discretion in denying evidentiary hearing); *Burns*, 3 F.3d at 417; *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 71500, at *2 (Fed. Cl. Spec. Mstr. Apr. 19, 1991).

ANALYSIS

I. Overview of Program Treatment of Brachial Neuritis

Although the Vaccine Injury Table only provides for a claim of brachial neuritis after receipt of the tetanus vaccine, special masters have on many occasions found that *other* vaccines—including the flu vaccine—might also be causal of the condition. *Morgan v. Sec'y of Health & Hum. Servs.*, No. 16-269V, 2023 WL 3984415 (Fed. Cl. Spec. Mstr. June 12. 2023) (finding two to three days post-intradermal influenza vaccination and the progression of pain and weakness over several days to be an acceptable temporal association); *Abels v. Sec'y of Health & Hum. Servs.*, No. 18-558V, 2022 WL 2036101 (Fed. Cl. Spec. Mstr. May 6, 2022) (flu vaccine deemed causal of brachial neuritis).

When adjudicating comparable claims, my own decisions have turned less on whether the vaccine at issue *could* cause brachial neuritis, and more on whether onset occurred in a medically acceptable timeframe. *See, e.g.*, *Greene v. Sec'y of Health & Hum. Servs.*, No. 11-631V, 2019 WL 4072110 (Fed. Cl. Spec. Mstr. Aug. 2, 2019) (finding that a 41-day onset after tetanus vaccine too long to be causal in Table claim), *mot. for rev. den'd*, 146 Fed. Cl. 655 (Fed. Cl. 2020), *aff'd*, 841 Fed. App'x. 195 (Fed. Cir. 2020); *Garner v. Sec'y of Health & Human Servs.*, No. 15-063V, 2017 WL 1713184 (Fed. Cl. Mar. 24, 2017), *mot. for rev. den'd*, 2017 WL 3483352 (Fed. Cl. July 31, 2017) (dismissing claim that the Hepatitis A and B vaccines caused brachial neuritis, where claimant reported arm or shoulder pain 45 days post-vaccination). I have not yet found brachial neuritis could not likely be caused by any particular vaccine—and acknowledge that persuasive case law suggests it can.

II. Petitioner Cannot Establish Entitlement

A foundational question raised by this claim is whether Petitioner in fact ever suffered from brachial neuritis—the alleged injury. Resolution of this issue will help resolve the matter. *Broekelschen*, 618 F.3d at 1347. Here, the overall record preponderates against brachial neuritis as the likely diagnostic explanation for her symptoms.

First, it is evident from records from the fall of 2019 that Petitioner was experiencing several concurrent symptoms, many of which (such as hand and wrist pain, later more likely

associated with CTS given her diagnosis in 2020) are inconsistent with brachial neuritis. G. Misamore et al., *Parsonage-Turner Syndrome (Acute Brachial Neuritis)*, 78-A J Bone Joint Surg Am 1405 (1996), filed as Ex. F2 (ECF NO. 23-4) (discussing the characteristic symptoms of brachial neuritis as the "sudden onset of severe pain in or about the shoulder girdle, followed shortly thereafter by weakness of at least on of the muscles about the shoulder"). In addition, other clinical findings and testing results were not confirmatory of the diagnosis. Thus, Petitioner's multiple physical exams from November 2019 to January 2020 did not reveal significant weakness or scapular winging. Ex. 2 at 144; Ex. 3 at 6. At the same time, the initial EMG/NCS studies produced no objective findings that would be confirmatory of brachial neuritis (but were wholly consistent with CTS). Ex. 2 at 144. Otherwise, the kinds of symptoms Petitioner experienced post-vaccination were consistent with her pre-vaccination status as well, further diminishing the possibility that she only began to undergo symptoms after the October 2019 vaccination.

At most, one treater (Dr. Dressler) speculated early on in Petitioner's course that brachial neuritis could be explanatory (and in connection with the flu vaccine). But that view was in part a function of Petitioner's self-reported symptoms, and also does not seem to have involved weighing Petitioner's presenting condition against her documented pre-vaccination cervical complaints. It also was not confirmed by subsequent testing. And the proposed diagnosis did not find later support among her treaters in 2020, and was not ultimately embraced. At the same time, Drs. Anand and Miner persuasively pointed out record evidence better supporting the alternative diagnoses of degenerative arthritis or cervical radiculopathy. Anand Supp. Rep. at 2; Miner Rep. at 3, 5.

In addition, even if the brachial neuritis diagnosis had possessed sufficient evidentiary support, Petitioner's claim would still not satisfy all three *Althen* prongs. This case turns on the third, timeframe prong.[7] The record evidence is inconsistent on when Petitioner first experienced onset of shoulder-related issues ostensibly associated with brachial neuritis—with some evidence (such as the first record from November 2019, in which brachial neuritis-like symptoms were reported) suggesting onset within a month of vaccination, while later on Petitioner began reporting onset within a day, or even *on the day of* vaccination. Ex. 3 at 26. Such an acute onset greatly decreases the likelihood of vaccine causation, since (as alluded to by Dr. Anand) an immune-mediated process would not manifest so quickly. (Anand Supp. Rep. at 2).[8] And nothing in Dr. Hixson's opinion or filed by Petitioner suggests otherwise.

[7] Because a claimant must satisfy all three prongs to prevail, I do not include analysis of Petitioner's success in establishing the first two *Althen* prongs (although as noted above, I acknowledge Program support for the contention that the flu vaccine "can cause" brachial neuritis).

[8] Indeed, even the Table claim of tetanus vaccine-caused brachial neuritis is not cognizable for onset occurring in less than *two* days post-vaccination. 42 C.F.R. § 100.3(a)(I)(B).

CONCLUSION

A Program entitlement award is only appropriate for claims supported by preponderant evidence. Here, Petitioner has not made such a showing. Petitioner is therefore not entitled to compensation.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[9]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[9] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.